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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,629	01/29/2004	Karla Weaver	10123/00901	6763
7590 Patrick J. Fay, Esq. FAY KAPLUN & MARCIN, LLP Suite 702 150 Broadway New York, NY 10038		EXAMINER SCHMIDT, EMILY LOUISE		
		ART UNIT 3767	PAPER NUMBER	
		MAIL DATE 02/25/2009		DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/768,629	WEAVER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Emily Schmidt	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 01 December 2008.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-7 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-7 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____ .	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 2 is objected to because of the following informalities: Claim 2 recites "...an annular base member wherein an area of the base membrane...". It is unclear if the recited base membrane is the same as the annular base member; there is insufficient antecedent basis for the limitation the base membrane. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The seating portion which covers a minority of the surface area of the lumen occluding portion in which the slit is disclosed as recited in the claims contains matter new to the application. Nowhere does the specification relate that the seating portion covers a minority of the surface area of the lumen occluding portion.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation of "...the thickness of the seating portion is greater than a thickness of the lumen occluding portion..." is unclear. The claim previously states that the seating portion is part of the flow control membrane. According to the specification, with references to the drawings member 102 is the flow control membrane. It is indefinite as to if the thickness of the seating portion is greater than a thickness of the lumen occluding portion regarding membrane 102 alone or when combined with membrane 104. For purposes of examination, it is interpreted that the overall thickness of the mounting portion when membranes 102 and 104 are combined that has a thickness greater than the lumen occluding portion. Additionally, the term minority has not been sufficiently defined. For purposes of examination, the term minority is taken to mean less than fifty percent.

#### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moorehead et al. (U.S. Patent 5,205,834) in view of Ohringer (U.S. Patent 3,811,466).

With regards to claim 1, Moorehead et al. teach a pressure activated slit for medical applications (Col. 2 line 10) comprising a housing having a lumen extending therethrough from a

proximal end to a distal end (Fig. 2 element 42), a flow control membrane (Fig. 5 elements 120, 124) including a mounting portion at which the flow control membrane is coupled to the housing (Fig. 5 element 120, Col. 6 lines 1-5) and a lumen occluding portion having a slit (Fig. 5 element 124, 146) extending therethrough so that, when the lumen occluding portion is subjected to a pressure of at least a predetermined threshold level, the lumen occluding portion moves from a closed configuration in which flow through the lumen is prevented to an open configuration in which flow is permitted (Col. 2 lines 29-32) and wherein a thickness of the mounting portion is greater than a thickness of the lumen occluding portion (Fig. 5 elements 120, 124, Col. 7 lines 17-20 base members add thickness to the mounting portion and not to the area encompassing the slit). Moorhead et al. further teach that the length of the slit is a variable set based on the desired pressure differential (Col. 7 lines 22-25 and 30-35) and that the size of the apertures in the discs surrounding the element are also variable and set based on the desired pressure differential required to open the slit (Col. 7 lines 33-35). Moorehead et al. does not specifically disclose the mounting portion to cover a minority of a surface area of the lumen occluding portion in which the slit is disposed. However, Ohringer teaches a slit diaphragm (Fig. 2 diaphragm 17) mounted between control plate 19 and flanges 13 and 15 and specifically teaches that by varying the diameter of the opening d3 in plate 19 surrounding the slit 31 you can control the flow through the slit. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to increase the size of the slit in Moorehead et al. in order to control the flow (Moorehead Col. 7 lines 22-25 and 30-35) and thereby increase the diameter of the mounting portion to accommodate the slit in the device in Moorehead et al. to further control the flow because Ohringer explicitly teaches that varying the diameter of an aperture around a slot is an

art recognized means for flow control. Ultimately, as the diameter of the aperture surrounding the slit is varied in an increasing manner to accommodate the slit and control the flow this would cause the mounting portion to cover a minority of the surface area.

With regard to claims 2 and 4, Moorehead et al. teach a flow control membrane composed of a first membrane (Fig. 5 element 124), an annular base membrane (Fig. 5 element 120) wherein an area of the base membrane substantially corresponds to that of the mounting portion and wherein the slit extends through the first membrane (Fig. 5). Moorehead et al. does not specifically teach bonding the first membrane to the annular base membrane, further, with regards to claim 4, Moorehead et al. does not teach adhesive bonding between membranes. However, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to adhesively bond the annular base (120) to a diaphragm (124) as such is an art recognized effective way of securing membrane layers together so as to maintain them in a desired position.

With regards to claim 3, Moorehead et al. teach a membrane retention portion of the housing, the membrane retention portion being adapted to apply a retentive compression force to mounting portion (Fig. 5 elements 90, 120, 124, Col. 6 lines 47-53). Additionally, the outer periphery of the membrane (Fig. 5 elements 120, 130) is contiguous with the housing (Fig. 5 element 90). Therefore, the housing is applying a compressive retentive force on the membrane, as the membrane is secured within the housing and not free to move.

8. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moorehead et al. (U.S. Patent 5,205,834) in view of Ohringer (U.S. Patent 3,811,466) as applied to claims 1 and 2 above, and further in view of Fischer et al. (U.S. Patent 5,944,698).

With regard to claims 5 and 6, Moorhead et al. teach a pressure activated valve substantially as claimed. Moorehead et al. differs from claims 5 and 6 in that it does not disclose specific thickness range for the membrane, though it does disclose that thickness variables are determined based on the pressure that will be experienced (Col. 7 lines 30-34). However, Fischer et al. teaches a membrane with a slit that opens due to fluid pressure as a result of a plunger being inserted into a syringe barrel (Fig. 3 elements 50, 52, Col. 6 lines 6-9) and that the membrane has a preferred thickness of about .01 inches to .05 inches (Col. 6 line 5). It would have been obvious to one of ordinary skill in the art to use membranes of a thickness of .01- .035 inches as in claim 5 or between .01 and .05 inches as in claim 6 as such is an art recognized membrane thickness range as exemplified in the teachings of Fischer et al. Moreover, the membrane thickness range is taken to be a result effective variable routinely optimized to correspond to the pressure the membrane will be exposed to.

With regard to claim 7, Moorhead et al. teach a pressure activated valve substantially as claimed. Moorehead et al. differs from claim 7 in that it does not teach the thickness of the mounting portion to be between 1 and 20 times the thickness of the lumen occluding portion. However, Fischer et al. teaches a preferred membrane thickness of about .01 to .05 inches (Col. 6 line 5). It would have been obvious to a person of ordinary skill in the art to apply the thickness range suggested in Fischer et al. to the membrane portions (Fig. 5 elements 122, 124) in

Moorehead et al. as applied to claims 5 and 6. It directly follows that the thickness of the mounting portion will be between 1 and 6 times the thickness of the lumen occluding portion.

***Response to Amendment***

9. The amendments to the claims have been entered.

***Response to Arguments***

10. Applicant's arguments filed December 1, 2008 have been fully considered but they are not persuasive. The Applicant has amended the claim to recite the seating portion instead of the mounting portion. This amendment is not sufficient to overcome all of the claim objections and rejections under 112. The Applicant has not addressed the recitation of the base membrane in claim 2. Further, the Applicant has not addressed the issues under 112 due to the amendment regarding the seating portion which covers a minority of a surface area of the lumen occluding portion or regarding the recitation that a thickness of the seating portion is greater than a thickness of the lumen occluding portion.

The Applicant has argued the combination of the Ohringer and Moorehead references. The Applicant has stated that Ohringer teaches preventing tearing of a slit and does not support expanding the diameter of an opening surrounding the slit and, further, Ohringer teaches expanding the size of the opening to a point which completely exposes the slit. The Examiner acknowledges Ohringer's teaching regarding preventing the tearing of a slit, however, the Examiner does not find this teaching to contradict or invalidate the teaching upon which the Examiner has relied. The Examiner has relied upon the teaching that the diameter d3 of the plate 19 surrounding the slit can be varied to control the flow (Col. 2 lines 50-51). The teaching

regarding varying the diameter  $d_3$  in order to control the flow is applied to the reference in Moorehead. The teaching of varying a diameter around a slit to control the flow remains valid and as such in the instance when increasing the diameter around the slit to control flow the corresponding seating portion would cover a minority of the surface area of the lumen occluding portion in which the slit is disposed. Further, the Applicant has stated that Ohringer supports expanding the size of the opening to a point which completely exposes the slit, Moorhead teaches varying the size of the slit and aperture to determine the pressure differentials which cause the slit to be opened. As Moorhead teaches varying the size of the slit and Ohringer supports creating an opening in which the slit is fully exposed, in the instance where the slit is expanded to allow for a pressure differential, Ohringer supports increasing the size of the aperture to fully expose the slit, the corresponding seating portion would cover a minority of the surface area of the lumen occluding portion in which the slit is disposed. Moorehead teaches varying the size of the slit and the opening, Ohringer is provided as further motivation as to altering the size of the opening which would result in the seating portion covering a minority of the surface area of the lumen occluding portion.

The Applicant has further argued that the references do not teach that the seating portion is coupled to the housing. Merriam-Webster defines coupled as to connect ("couple." Merriam-Webster Online Dictionary. 2009. Merriam-Webster Online. 23 February 2009 <http://www.merriam-webster.com/dictionary/couple>). The Examiner has taken elements 120 and 124 in the device of Moorehead to construe the flow control membrane which are connected to housing 42. This membrane, including the seating portion is effectively coupled to, connected to, the housing (Fig. 2).

***Conclusion***

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Schmidt whose telephone number is (571) 270-3648. The examiner can normally be reached on Monday through Thursday 7:30 AM to 5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 3767  
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